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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,063	01/28/2002	Norihito Shimono	2002-0055A	8747
513	7590	01/31/2006		
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/048,063	Applicant(s) SHIMONO ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 11/7/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of by Lerner et al (USPN 5,840,332 hereafter '332). The claims are drawn to a solid product comprising a core, first layer comprising a water-insoluble polymer having chitosan dispersed therein, and an enteric coating.

4. The '332 patent discloses a solid formulation comprising a core and successive coatings (abstract). The coating composition comprises a water-insoluble carrier with a particulate dispersed therein (col. 9, lin. 38-65). The particulate matter is chitosan, and the water-insoluble include well known such as various Eudragit polymers along with ethylcellulose (*Ibid.*). The form further comprises an enteric coating (claim 4). The enteric coating comprises well-known enteric polymers including those based on methacrylic acid and methyl methacrylate copolymer (claim 17). The dosage form comes as a tablet, or pill, or capsule (abstract), and is designed for colonic delivery (col. 6, lin. 57-65). The reference teaches method of producing the coatings including

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dispersing the solid particulates in the water-insoluble polymer and coating a core pellet (examples).

5. Regarding claims 1 and 7, it is the position of the Examiner that these claims represent product-by-process claims, and as such patentable weight is not given to their process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

6. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

7. As discussed above the ‘332 reference discloses a solid formulation comprising a core with a successive coating of a water insoluble polymer with chitosan dispersed therein. The reference is silent however to the specific ratio of the particulate matter to that of the water-insoluble polymer. The reference teaches that this ratio is important in

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order to control the rate of the release of the drug (col. 11, lin. 50-55). Under this suggestion, it is the position of the Examiner that such a feature would be well within the level of skill in the art to determine through routine experimentation. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

See In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

8. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality.

See In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

9. With these things in mind it would be well within the level of skill in the art to follow the teachings and suggestions of '332 in order to produce a solid colonic dosage form. The artisan of ordinary skill would have been motivated to follow these teachings and disclosures with an expected result of a solid formulation useful for colic sustained delivery of active agents.

Response to Arguments

10. Applicant's arguments filed 11/7/05 have been fully considered but they are not persuasive. Applicant argues that:

- a. Lerner does not obviate the claims and there is no motivation to modify the disclosures.

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11. Regarding argument a., it remains the position of the Examiner that the Lerner reference obviates the instant claims. The claims are drawn to a solid dosage form comprising a core and successive coating of a water-insoluble polymer with particulate matter, specifically chitosan, dispersed throughout, followed by an enteric coating. The Lerner reference teaches a solid dosage form, with a core, coated with a water-insoluble polymer with particulates dispersed throughout. The dosage form is then coated with enteric polymers. Among the many particulates named as useful in the invention chitosan is named among specific particulate manner included in the invention (col. 9, lin. 45-48; claims 1-4).

12. Applicant attempts to argue that the disclosure of Lerner is misinformed, however that determination is improper since all patents are deemed valid unless proven in court of law. For the purposes of this prosecution, the disclosures of Lerner are taken at face value and are taken by the Examiner to obviate the instant claims. Further Applicant provides arguments that under different conditions the chitosan of the reference would be water-soluble. However these conditions are not met or discussed in the reference. Due to this it is assumed that the chitosan remains as applicant intends for the chitosan to be used.

13. In summation, the Lerner reference teaches a solid dosage form with a coating comprising solid particulate matter. The solid particulate matter is disclosed to be chitosan. It is disclosed that the ratio of the particulate matter to the polymer is a major factor in determining the release of the drug in the core. These disclosure and teachings would motivate the artisan of ordinary skill to manipulate and optimize the ratios in order to achieve the best or desired release of the drug. The Office does not have the facilities

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for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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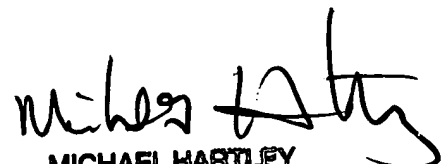
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL HARTLEY
PRIMARY EXAMINER